

What is claimed is,

1. A prosthesis containing a rupture indicator comprising:
 - (a) an external envelope of medical grade elastomer containing a fluid material and a biologically compatible chemical indicator for indicating rupture of said prosthesis, and
 - (b) an internal envelope of medical grade elastomer disposed within said external envelope, said internal envelope containing an implant filling material.
- 10 2. The prosthesis containing a rupture indicator of Claim 1, wherein said biologically compatible chemical indicator is a dye.
3. The prosthesis containing a rupture indicator of Claim 2, wherein said biologically compatible chemical indicator is methylene blue.
- 15 4. The prosthesis containing a rupture indicator of Claim 2, wherein said biologically compatible chemical indicator is at least one selected from the group consisting of aurintricarboxylic acid (ATA), halogenated ATA, sulfonated ATA, sulfonated-halogenated ATA, phosphorylated ATA, anazolene sodium, eosine I bluish, eosine yellowish, erythrosine, Evan's blue (EB), fast green FCF, fuchin(e) acid, iodophthalein sodium, rose bengal, sulfobromophthalein sodium, suramin sodium, trypan blue, trypan red, rosaniline chloride, crystal violet, methyl blue, methyl green, coomassie blue, basic fuchsin, malachite green, brilliant green,

aniline blue, brilliant cresyl blue, safranin O, ethyl violet, pararosaniline acetate, methyl violet, direct yellow, direct red,ponceau S, ponceau SS, nitrosulfonazo III, chicago sky blue 6B, calcion or RG-13577, FD&C red No. 3, FD&C red No. 40, FD&C blue No. 1 and FD&C yellow No. 5.

5

5. The prosthesis containing a rupture indicator of Claim 1, wherein said biological compatible chemical indicator is an odour generating agent which generates a smell when leaking out from said prosthesis.

10

6. The prosthesis containing a rupture indicator of Claim 1, wherein said biological compatible chemical indicator is a sensation agent which causes a local sensation when leaking out from said prosthesis.

15

7. The prosthesis containing a rupture indicator of Claim 1, wherein said prosthesis is a breast prosthesis.

8. The prosthesis containing a rupture indicator of Claim 1, wherein said prosthesis is at least one selected from the group consisting of brow, nose, cheek, chin, lips, pectoral, triceps and biceps, genitals, buttocks and calf prostheses.

20

9. The prosthesis containing a rupture indicator of Claim 1, wherein said external lumen further comprises a filling means for filling said fluid material.

10. The cosmetic and reconstructive prosthesis containing a rupture indicator of Claim 9, wherein said filling means is a self-sealing valve.

11. A method of detecting rupture of a cosmetic and reconstructive
5 prosthesis comprising:

(a) surgically implanting a prosthesis containing a biologically compatible chemical indicator for indicating rupture of said prosthesis in a location of a patient body in need of said prosthesis; and

10 (b) detecting a change of a body secretion or peripheral blood for indication of leaking out of said indicator from said prosthesis.

12. The method of Claim 11, wherein said body secretion is at least one selected from the group consisting of urine, saliva, perspiration and feces.

15 13. The method of Claim 12, wherein said change is a presence of said chemical indicator or metabolized product thereof in said body secretion or peripheral blood.

14. The method of Claim 12, wherein said change is an odour from said
20 indicator in said body secretion.

15. The method of Claim 12, wherein said change is a color change of at least one of said body secretion.

16. A method of detecting rupture of a cosmetic and reconstructive prosthesis comprising:

- (a) surgically implanting a prosthesis containing a biologically compatible chemical indicator for indicating rupture of said prosthesis in a location of a patient body in need of said prosthesis; and
- (b) detecting a change locally around said prosthesis for indication of leaking out of said indicator from said prosthesis.

10 17. The method of Claim 16, wherein said change is a local skin color change.

18. The method of Claim 16, wherein said change is a local sensation.

15 19. The method of Claim 16, wherein said change is a local x-ray opacity change from that after said surgically implanting said prosthesis.